DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 4, 2015

Etiometry, Inc.
% Pamela Weagraff
Director And Practice Lead
Quintiles Consulting
18 Bridie Lane
Norfolk, Massachusetts 02056

Re: K142732
Trade/Device Name: T3 Software
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: January 29, 2015
Received: January 30, 2015

Dear Pamela Weagraff,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142732

Device Name
T3 Software Solution

Indications for Use *(Describe)*
The T3 Software is intended for the recording and display of multiple physiological parameters of adult, pediatric and neonatal patients from supported bedside devices. T3 is not intended for alarm notification or waveform display, nor is it intended to control any of the independent bedside devices to which it is connected. T3 is intended to be used by healthcare professionals for the following purposes:

• To remotely consult regarding a patient's status, and
• To remotely review other standard or critical near real-time patient data in order to utilize this information to aid in clinical decisions and deliver patient care in a timely manner.

T3 can display numeric physiologic data captured by other medical devices:

• Airway flow, volume and pressure
• Arterial blood pressure (invasive and non-invasive, systolic, diastolic, and mean)
• Bispectral index (BIS, signal quality index, suppression ratio)
• Cardiac Index
• Cardiac output
• Central venous pressure
• Cerebral perfusion pressure
• End-tidal CO2
• Heart rate
• Heart rate variability
• Intracranial pressure
• Left atrium pressure
• Oxygen saturation (intravascular, regional, SpO2)
• Premature ventricular counted beats
• Pulmonary artery pressure (systolic, diastolic, and mean)
• Pulse pressure variation
• Pulse Rate
• Respiratory rate
• Right atrium pressure
• Temperature (rectal, esophageal, tympanic, blood, core, nasopharyngeal, skin)
• Umbilical arterial pressure (systolic, diastolic, and mean)

WARNING: T3 Software is not an active patient monitoring system; it is intended to supplement and not replace any part of the hospital's device monitoring. Do not rely on the T3 Software as the sole source of patient status information.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS - K142732

[Format according to Appendix C – "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", July 28, 2014 to meet requirements of Title 21 CFR Part 807.92]

1) **510(k) Submitter**:

   a) Company Name and Address:

   Etiometry, Inc.
   119 Braintree Street
   Boston, MA 02134

   b) Company Contact: Dimitar Baronov, PhD Chief Technology Officer
   Phone: 857.366.9333 ext. 2005
   E-mail: baronov@etiometry.com

   c) Date Prepared: February 25, 2015

2) **Device**

   a) Device Trade Name: T3 Software

   b) Device Common/Usual Name: Data Management Software (without alarms)

   c) Classification Name: Cardiac monitor (including cardiotachometer and rate alarms

   d) Classification Number: 870.2300

   e) Regulatory Class: II

   f) Product Code: MWI; monitor, physiological, patient (without arrhythmia detection or alarms)

3) **Predicate Device**

   a) Vital Sync™ Informatics Manager has been cleared under K140339, K132604, K123002, and K093422.

   b) Vital Sync™ Informatics Manager is subject of two software design-related recalls, Z-2234-2014 and Z-2235-2014.

4) **Device Description**

The Tracking, Trajectory, Trigger *(T3)* intensive care unit software solution allows clinicians and quality improvement teams in the ICU to aggregate data from multiple sources, store it in a database for analysis, and view the streaming data in real-time. System features include:

- Customizable display of physiologic parameters over entire patient stay
- Configurable annotation
- Web-based visualization that may be used on any standard browser
- Minimal IT footprint
- Software-only solution – no new bedside hardware required
- Highly reliable and robust operation
- Auditable data storage

The T3 Software is intended for the display and recording of multiple physiological parameters of adult, pediatric and neonatal patients. T3 is not intended for alarm notification or waveform display, nor is it intended to control any of the independent bedside devices to which it is connected.

The T3 software can display user-defined, derived measures. These measures include the percentage of time within a time period that a particular variable is above or below a threshold. The user can configure the time period, threshold, and label of the resulting derived measure for ease of use considerations, only.

The T3 Software is not an active patient monitoring system. It is intended to supplement and not replace any part of the hospital's device monitoring.

T3 has a web architecture consisting of a user interface that runs in a browser, and a central web server. The T3 server, a set of cooperating web services written in Java, processes data as it is received, caches it in memory, and writes out copies of the data to a relational database and to the file system. In this manner, the data is available to the user interface to be visualized by the end user – a clinician.

Clinicians access the T3 user interface in a web browser. T3 runs in current browsers that support HTML5, Javascript and web sockets, such as Chrome, Firefox, Safari and Internet Explorer. The clinicians may be in the hospital, or may be outside the hospital accessing T3 over a Virtual Private Network (VPN). Clinicians use T3 in addition to the physiometric devices themselves and other information sources such as the electronic medical record to monitor the patient’s condition.

5) **Indications for Use**

The T3 Software is intended for the recording and display of multiple physiological parameters of adult, pediatric and neonatal patients from supported bedside devices. T3 is not intended for alarm notification or waveform display, nor is it intended to control any of the independent bedside devices to which it is connected.

T3 is intended to be used by healthcare professionals for the following purposes:

- To remotely consult regarding a patient's status, and
- To remotely review other standard or critical near real-time patient data in order to utilize this information to aid in clinical decisions and deliver patient care in a timely manner.

T3 can display numeric physiologic data captured by other medical devices:

- Airway flow, volume and pressure
- Arterial blood pressure (invasive and non-invasive, systolic, diastolic, and mean)
- Bispectral index (BIS, signal quality index, suppression ratio)
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- End-tidal CO2
- Heart rate
- Heart rate variability
- Intracranial pressure
- Left atrium pressure
- Oxygen saturation (intravascular, regional, SpO2)
- Premature ventricular counted beats
- Pulmonary artery pressure (systolic, diastolic, and mean)
- Pulse pressure variation
- Pulse Rate
- Respiratory rate
- Right atrium pressure
- Temperature (rectal, esophageal, tympanic, blood, core, nasopharyngeal, skin)
- Umbilical arterial pressure (systolic, diastolic, and mean)

WARNING: T3 Software is not an active patient monitoring system; it is intended to supplement and not replace any part of the hospital's device monitoring. Do not rely on the T3 Software as the sole source of patient status information.

The T3 Software indications for use differ from the Vital Sync™ in that T3 Software does not interface to the EMR or CIS and does not display alarms or waveforms. As a result the T3 Software does not introduce differences which would result in a change in safety or effectiveness as compared to the predicate Vital Sync system.

The indications for use are the same with respect to the near real-time data recording and remote display capabilities. Neither the T3 Software nor the Vital Sync™ is intended to replace any part of the hospitals device monitoring systems; and are also not intended to be used as the sole source of information in the care of the patient.

6) **Comparison of Technological Characteristics with the Predicate Device**

The T3 Software has similar features and functionality as the predicate Vital Sync system with the exception of the differences noted above. The systems are web based and designed to acquire data from the network source and display the information remotely for clinicians to use in the care of their patients. The technological characteristics implemented in T3 software to achieve this interaction are similar to the predicate device as well. Please refer to Table 1 below:

Table 1: Comparison of Technological Characteristics

	T3 Software	**Predicate – Vital Sync™ Informatics Manager**
Regulation Number / Product Code	Cardiac monitor (including cardiotachometer and rate alarm) 21 CFR 870.2300 / MWI	Cardiac monitor (including cardiotachometer and rate alarm) 21 CFR 870.2300 / MWI
Server	» Server: 1 » CPU: 2x Intel Xeon E5649 or better (6 core 2.53GHz) » RAM: 48 GB » Hard Drive: 1 TB usable » External Storage: per hospital policy back-up policies and procedures » OS: Red Hat Enterprise Linux 6 or Higher » Software: Installs and uses PostgreSQL 9.1	» Server: 1 » CPU: 1 – 3.46 GHz, 12M Cache, 6.40 GT/s QPI, 6 Core » RAM: 4 GB » Hard Drive: 500 GB » External Storage: external tape back-up for data archive » OS: Windows® Server 2008 R2 Enterprise » Software: IIS 7.0, Sql Server 2008 R2, .Net 4.0, ReportViewer V10.0
Remote Viewing Device	» Software Browser: requires HTML5 support, such as Chrome, Internet Explorer 11, Firefox 30, Safari 5 » CPU: 2.5 GHz Core 2 Duo Processor or equivalent » RAM: 2 GB » Video Display: 1024 x 768	Software Browser: Internet Explorer 9, Firefox 10, Safari 5.1
Network	Server Environment: 1000Mb/s Browser connection to server: 10Mb/s	Server Environment: 100/1000 Mbps Ethernet
Wireless Network	Individual users require a rate of 10Mb/s	Minimum available bandwidth in Kbs: X*2.1+Y*148 where X = Number of active devices Y = Number of active display devices Any hardware purchased must be supported by the hospital IS department (Reference Recommended Wi-Fi Device Specification).

Table 1: Comparison of Technological Characteristics

	T3 Software	**Predicate – Vital Sync™ Informatics Manager**
Other	Uninterruptible power supply (one per server)	» Uninterruptible power supply (one per server) » DVD reader is required for installation of SW on the server. » Isolation transformer or a 60601 certified power strip is required to enable a single power connection from the ventilator to the power supply if a powered Wi-Fi device is used.
Use Environment	Hospital	Hospital
Displayed Parameters	All display parameters provided by Philips Intellibridge	All display parameters provided by Covidien bedside devices
Externally Supported Devices	Philips Intellibridge	Covidien bedside devices

7) **Performance Data**

In support of this 510(k) premarket notification, Etiometry has conducted software verification and validation testing. T3 Software documentation has been provided in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005. T3 Software is considered a moderate level of concern since a malfunction of, or a latent design flaw in, the Software Device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury.

Software verification and validation testing consisted of unit tests, integration and manual performance tests. Individual test cases were defined for each software requirement, including test execution steps, acceptance criteria and test methodology. Upon successful completion of unit testing, automated integration testing was performed followed by manual performance testing.
Unscripted exploratory testing was performed to confirm that the system responded as intended and met all performance specifications. Software verification and validation results confirmed that T3 Software functions as intended and meets all performance specifications.

T3 Software is a software medical device, therefore biocompatibility testing, electrical safety and electromagnetic compatibility (EMC) testing, sterilization, shelf-life, animal testing and clinical testing were not required to demonstrate substantial equivalence.

8) **Substantial Equivalence Conclusion**

Substantial equivalence of the T3 Software is demonstrated through performance testing and shows that the T3 software solution is as safe and effective as Vital Sync™ Informatics Manager, cleared under K140339, K132604, K123002, and K093422. The T3 software solution has the same intended uses and similar indications, technological characteristics, and principle of operation as its predicate device.

The minor technological differences between the T3 Software and its predicate device do not raise any new safety or effectiveness questions. Performance data demonstrate that the T3 Software is safe and effective to perform its intended use to record and display multiple physiological parameters of adult, pediatric and neonatal patients from supported bedside devices. T3 is not intended for alarm notification or waveform display, nor is it intended to control any of the independent bedside devices to which it is connected.

WARNING: T3 Software is not a real-time patient monitoring system; it is intended to supplement and not replace any part of the hospital's active patient monitoring system. Do not rely on the T3 Software as the sole source of patient status information.

Therefore, T3 Software is substantially equivalent to its predicate device.